CASE 4-18634

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE U.S. PATENT NO. 5,677,331
ISSUED: October 14, 1997
INVENTORS: Yiqing Zhou, Dianxi Ning, Shufen Wang, Deben Ding, Guofu Li, Chengqi Shan, and Guangyu Liu
FOR: ANTIMMALARIAL COMPOSITIONS

Mail Stop: Hatch-Waxman PTE
Director for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C.§156

Sir:

Applicant previously submitted an application under 35 USC §156 requesting extension of the term of the above-identified U.S. Patent No. 5,677,331. The request for extension was certified on June 5, 2009.

As discussed with Ms. Mary C. Till at the USPTO, submitted herewith are:

(1) Statement Under 37 CFR 3.73(b); and

(2) Power of Attorney of Revocation of Power of Attorney and Change of Correspondence Address;

which are signed by both co-owners of U.S. Patent 5,677,331: Novartis AG and Institute of Microbiology and Epidemiology, Academy of Military Medical Sciences.

In addition, upon review by the Applicant and as noted by Ms. Mary C. Till during a telephone call, an inadvertent typographical error in the above-referenced application is discovered. Specifically, the structure of Artemether on page 2 is missing an oxygen atom.

Applicant hereby submits a Corrected Patent Term Extension Application Under 35 U.S.C.§156 to illustrate the correct chemical structure for Artemether. This typographical error had no material bearing on the substantive review of the patent term extension application as the correct structure of Artemether is illustrated at page 12 of the approved label previously submitted.

Applicant wishes to take this opportunity to thank Ms. Till for her careful review of the request and communication with the undersigned.

Respectfully submitted,

Jennifer C. Chapman

Jennifer C. Chapman
Attorney for Applicant
Reg. No. 47,487
(862) 778-1202

Novartis
Patents Pharma
One Health Plaza, Building 101
East Hanover, NJ 07936-1080

Date: November 16, 2009

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Novartis AG

Application No./Patent No.: ~~08/216,440 /5,677,331~~ Filed/Issue Date: March 23, 1994/Oct14, 1997

Titled: ANTIMALARIAL COMPOSITIONS

Institute of Microbiology and Epidemiology, Academy of Military Medical Sciences/ Novartis/AG, a University/Corporation

(Name of Assignee) (Type of Assignee, e.g. corporation partnership university government agency etc.)

states that it is:

1. ☐ the assignee of the entire right, title, and interest in;

2. ☐ an assignee of less than the entire right, title, and interest in
(The extent (by percentage) of its ownership interest is _____ %), or

3. ☐ the assignee of an undivided interest in the entirety of a complete assignment from one of the joint inventors was made in the patent application/patent identified above, by virtue of either:

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B. ☒ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Zhou, Yiqing et al. To: Ciba-Geigy AG/Institute of ~~Microbiology & Epidemiology~~

The document was recorded in the United States Patent and Trademark Office at
Reel 008557, Frame 0400, or for which a copy thereof is attached.

2. From: ~~Ciba-Geigy AG~~ To: ~~Novartis AG~~

The document was recorded in the United States Patent and Trademark Office at
Reel 011072, Frame 0019, or for which a copy thereof is attached.

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☐ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Jennifer Chapman — Oct. 15, 2009
Signature — Date

Cao, Wuchun/Jennifer Chapman — Director/Patent Attorney
Printed or Typed Name — Title

PTO/SB/81 (01-09)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	08/216,440
Filing Date	March 23, 1994
First Named Inventor	Yiqing Zhou
Title	ANTIMALARIAL COMPOSITIONS
Art Unit	1614
Examiner Name	Jordan, Kimberly R.
Attorney Docket Number	18634-US-CNT2

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

01095

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name

Address	
City	State / Zip
Country	
Telephone	Email

I am the:

☐ Applicant/Inventor.

OR

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on

SIGNATURE of Applicant or Assignee of Record

Signature	Date: Oct. 15, 2009
Name	Cao, Wuchun/Jennifer Chapman — Telephone: 862 778-1202
Title and Company	Institute of Microbiology and Epidemiology, Academy of Military Medical Sciences/Novartis AG

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

CASE 4-18634

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

Express Mail Label Number

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE U.S. PATENT NO. 5,677,331
ISSUED: October 14, 1997
INVENTORS: Yiqing Zhou, Dianxi Ning, Shufen Wang, Deben Ding, Guofu Li, Chengqi Shan, and Guangyu Liu
FOR: ANTIMMALARIAL COMPOSITIONS

Mail Stop: Hatch-Waxman PTE
Director for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CORRECTED PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C.§156

Sir:

Pursuant to 35 U.S.C.§156 and 37 C.F.R.§1.710 *et seq.*, Novartis AG ("Applicant"), a Corporation organized under the laws of Switzerland, hereby requests an extension of the patent term due to regulatory review of U.S. Patent No. 5,677,331, which was granted on October 14, 1997.

Applicant asserts that it is the co-owner of the right, title and interest in U.S. Patent No. 5,677,331 by virtue of an assignment from the inventors Yiqing Zhou, Dianxi Ning, Shufen Wang, Deben Ding, Guofu Li, Chengqi Shan, and Guangyu Liu, to Ciba-Geigy AG (which later becomes part of Novartis AG through a merger) and Institute of Microbiology, Academy of Military Medical Sciences.

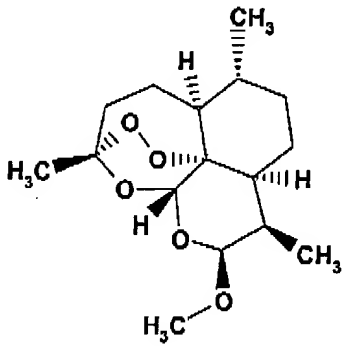
The assignment and the merger are recorded in the U.S. Patent and Trademark Office at Reel 008557, Frame 0400 on June 19, 1997 and Reel 011072, Frame 0019 on October 31, 2000, respectively.

Applicant asserts that the undersigned counsel, Jennifer C. Chapman, is authorized to act as its attorney in this matter.

In accordance with 35 U.S.C.§156 and 37 C.F.R.§1.740, Applicant provides the following information in support of its request for a patent term extension.

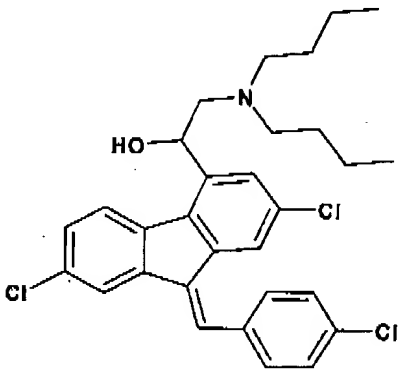
(1) **Identification of the Approved Product**

The approved product is Coartem®, which is a fixed combination of two antimalarial active ingredients: artemether and lumefantrine, having the chemical structure(s)



Artemether

and



Lumefantrine

respectively.

The chemical name of artemether is (3R,5aS,6R,8aS,9R,10S,12R,12aR)-decahydro-10-methoxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-benzodioxepine.

The chemical name of lumefantrine is (±)-2-dibutylamine-1-[2,7-dichloro-9-(4-chlorobenzylidene)-9H-fluorene-4-yl]ethanol.

The strength is 20mg/120mg, artemether / lumefantrine respectively.

The approved product is a tablet for oral administration.

The approved product is indicated for the treatment of acute, uncomplicated malaria infection due to *Plasmodium falciparum* in patients of 5 kg bodyweight and above.

A copy of the approved label for Coartem® is attached hereto as Appendix A.

2. **Identification of the Federal Statute under which Regulatory Review Occurred**

The approved product was subject to regulatory review under the Federal Food, Drug and Cosmetic Act, Section 505(b) (21 U.S.C.§355(b)).

3. **The Date of Permission for Commercial Marketing**

The approved product received permission for commercial marketing under Section 505(c) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.§355(c)) on April 7, 2009. A copy of the FDA approval letter is attached hereto as Appendix B.

4. **Active Ingredient Statement**

There are two active ingredients in Coartem®: artemether and lumefantrine.

Neither artemether nor lumefantrine has been previously approved for commercial marketing or use under Section 505 of the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or the Virus-Serum Toxin Act prior to the approval of NDA 22-268 by the United States Food and Drug Administration on April 7, 2009.

5. **Statement of Timely Filing**

The last day on which this application could be submitted is June 6, 2009 which is 60 days after the approval of NDA 22-268 on April 7, 2009. This application is timely filed on or prior to June 6, 2009.

6. **Identification of Patent for which Extension is Sought**

This application seeks to extend the term of U.S. Patent No. 5,677,331, which issued October 14, 1997 to Yiqing Zhou, Dianxi Ning, Shufen Wang, Deben Ding, Guofu Li, Chengqi Shan, and Guangyu Liu, the term of which would otherwise expire on October 14, 2014.

7. **Patent Copy**

A complete copy of U.S. Patent No. 5,677,331, identified in paragraph 6 above, is attached as Appendix C.

8. **Post-Issuance Activity Statement**

No disclaimer, certification of correction, reexamination certificate or reissue has been filed, issued or requested with respect to U.S. Patent No. 5,677,331.

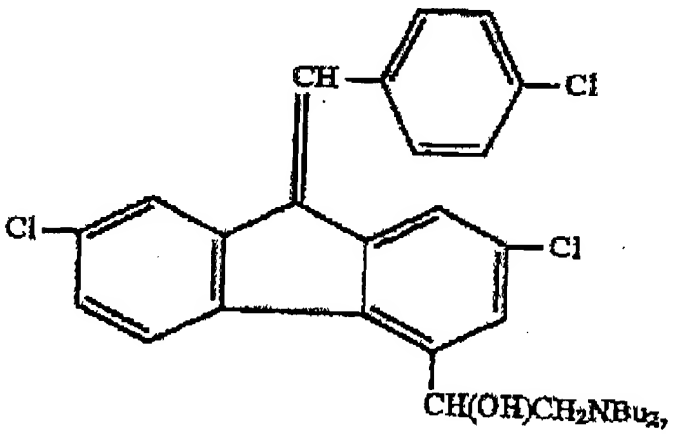
All maintenance fees have been timely paid. The 4th year maintenance fee was paid on April 2, 2001. The 8th year maintenance fee was paid on April 1, 2005. The 12th year maintenance fee was paid on March 18, 2009. Copies of the Maintenance Fee Statements are attached hereto as Appendix D.

9. **Statement Showing How the Claims of the Patent for which Extension is Sought Cover the Approved Product**

The claims of U.S. Patent No. 5,677,331 cover the approved product (claims 1-4), and a method of using the approved product (claim 5).

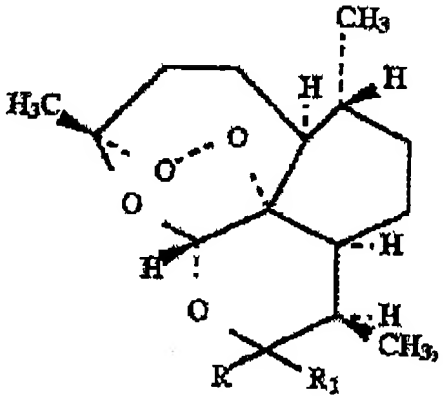
Claim 1 of U.S. Patent No. 5,677,331 reads as follows:

> 1. A pharmaceutical composition to be administered orally to humans, suitable for synergistic action of the combined active components against malaria, which composition consists of a synergistic antimalarially effective amount of a combination of the compound benflumetol of the formula:



(I)

in fixed combination with the compound artemether of the formula:



(II)

wherein one of R and R_1 individually represents methoxy, and the other represents hydrogen,

and pharmaceutically acceptable additives.

The approved product is a fixed combination of artemether (as in formulation (II) of claim 1 of U.S. Patent No. 5,677,331) and lumefantrine (as in formulation (I) of claim 1 of U.S. Patent No. 5,677,331). The approved product is an oral dosage form, and it is for the treatment of malaria. Hence, claim 1 covers the approved product.

Claim 2 of U.S. Patent No. 5,677,331 reads as follows:

2. A pharmaceutical composition according to claim 1, which composition consists of a synergistically effective amount of one to ten parts by weight of benflumetol (I) for each part by weight of artemether (II).

Coartem® tablets contain 20mg of artemether and 120mg of lumefantrine. The weight ratio of lumefantrine/artemether is 6, between 1 to 10 as required by claim 2. Hence claim 2 covers the approved product.

Claim 3 of U.S. Patent No. 5,677,331 reads as follows:

3. A pharmaceutical composition according to claim 1, which composition consists of a synergistically effective amount of three to seven parts by weight of benflumetol (I) for each part by weight of artemether (II).

Coartem® tablets contain 20mg of artemether and 120mg of lumefantrine. The weight ratio of lumefantrine/artemether is 6, between 3 to 7 as required by claim 3. Hence claim 3 covers the approved product.

Claim 4 of U.S. Patent No. 5,677,331 reads as follows:

4. A pharmaceutical composition according to claim 1 which composition consists of a synergistically effective amount of five to six parts by weight of benflumetol (I) for each part by weight of artemether (II).

Coartem® tablets contain 20mg of artemether and 120mg of lumefantrine. The weight ratio of lumefantrine/artemether is 6, between or equal to 5 to 6 as required by claim 3. Hence claim 3 covers the approved product.

Claim 5 of U.S. Patent No. 5,677,331 reads as follows:

5. A method of treating malaria which comprises administering orally to a human in need of such treatment a synergistic antimalarially effective amount of a combination of benflumetol of formula (I) and artemether of formula (II).

The approved product is indicated for the treatment of acute, uncomplicated malaria infection due to *Plasmodium falciparum* in patients of 5 kg bodyweight and above. Hence, claim 5 covers the method of using the approved product.

10. Statement of the Relevant Dates to Determine the Regulatory Review Period

The relevant dates and information pursuant to 35 U.S.C.§156(g) to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

The patent for which extension of the term thereof is sought claims a human drug product. The human drug product is a composition containing artemether and lumefantrine.

(A) No investigational new drug (IND) application was filed prior to the approval of the approved product. An IND was filed after the approval of the approved product in order to submit post-approval data. The IND number is 105,588.

(B) A New Drug Application (NDA) for Coartem® was received by the Department of Health and Human Services on June 27, 2008 and granted NDA No. 22-268.

(C) NDA No. 22-268 was approved on April 7, 2009.

11. Brief Description of Activities Undertaken During the Regulatory Review Period

As a brief description of the activities undertaken during the applicable regulatory review period, attached hereto as Appendix E is a chronology of the major communications between the U.S. Food and Drug Administration and the Applicant in NDA No. 22-268.

12. **Opinion of Eligibility for Extension**

Applicant is of the opinion that U.S. Patent No. 5,677,331 is eligible for extension under 35 U.S.C.§156 and 37 C.F.R.§1.720 because it satisfies all of the requirements for such extension as follows:

(a) 35 U.S.C.§156(a) and 37 C.F.R.§1.720(a)

U.S. Patent No. 5,677,331 claims a human drug product, a pharmaceutical composition containing fixed combination of two active ingredients artemether and lumefantrine.

MPEP 2751 states:

"A patent is considered to claim the product at least in those situations where the patent claims the active ingredient per se, or claims a composition or formulation which contains the active ingredient(s) and reads of the composition or formulation approved for commercial marketing or use"

(b) 35 U.S.C.§156(a)(1) and 37 C.F.R.§1.720(a)

The term of U.S. Patent No. 5,677,331 (expiring October 14, 2014) has not expired before the submission of this application.

(c) 35 U.S.C.§156(a)(2) and 37 C.F.R.§1.720(b)

The term of U.S. Patent No. 5,677,331 has never been extended.

(d) 35 U.S.C.§156(a)(3) and 37 C.F.R.§1.720(c)

The application for extension of the term of U.S. Patent No. 5,677,331 is submitted by the authorized attorney of the co-owner of record thereof in accordance with the requirements of 35 U.S.C.§156(d) and 37 C.F.R.§1.740.

(e) 35 U.S.C.§156(a)(4) and 37 C.F.R.§1.720(d)

The approved product, Coartem®, has been subjected to a regulatory review period before its commercial marketing or use.

(f) 35 U.S.C.§156(a)(5)(A) and 37 C.F.R.§1.720(h)

No other patent has been extended for the same regulatory review period for the approved product, Coartem®.

13. **Length of extension claimed under 37 C.F.R.§1.740(a)(12)**

The length of extension of the patent term of U.S. Patent No. 5,677,331 requested by Applicant is 284 days (till July 25, 2015) which length was calculated in accordance with 37 C.F.R.§1.775 as follows:

(a) The regulatory review period under 35 U.S.C.§156(g)(1)(B) began on June 27, 2008 (the effective date of the NDA) and ended on April 7, 2009 (the approval date), amounting to a total of 284 days which is the period of (i) and (ii) below:

(i) The period of review under35 U.S.C.§156(g)(1)(B)(i), the "Testing Period," which is 0 days;

(ii) The period of review under 35 U.S.C.§156(g)(1)(B)(ii), the "Application Period," began on June 27, 2008 and ended on April 7, 2009, which is 284 days;

(b) The regulatory review period upon which the period for extension is calculated is the entire regulatory review period as determined in subparagraph (13)(a) above (284 days) less:

(i) The number of days in the regulatory review period which were on or before the date on which the patent issued (October 14, 1997), i.e., 0 days, and

(ii) The number of days during which the Applicant did not act with due diligence, i.e., 0 days, and

(iii) One-half of the number of days remaining in the period in subparagraph (13)(a)(i) after subtracting the number of days in subparagraphs (13)(b)(i) and (13)(b)(ii), which is one-half of (0 - [0 + 0]) or 0 days;

which results in a period of 284-0=284 days.

(c) The number of days as determined in subparagraph (13)(b), when added to the original term (October 14, 2014), would result in the date of July 25, 2015.

(d) Fourteen (14) years when added to the date of the NDA Approval Letter (April 7, 2009) would result in the date of April 7, 2023.

(e) The earlier date as determined by subparagraphs (13)(c) and (13)(d) is July 25, 2015.

(f) Since the original patent was issued after September 24, 1984, the extension otherwise obtainable is limited to not more than five (5) years. Five years, when added to the original expiration of U.S. Patent No. 5,677,331 (October 14, 2014), results in the date October 14, 2019.

(g) The earlier date as determined in subparagraphs (13)(e) and (13)(f) is July 25, 2015.

14. **Duty of Disclosure Acknowledgement Under 37 C.F.R.§1.740(a)(13)**

Applicant acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

15. **Fee Charge**

The prescribed fee for receiving and acting upon this application is to be charged to Applicant's Deposit Account No. 19-0134 as authorized in the attached transmittal letter, submitted in triplicate.

16. **Correspondence Address Required by 37 C.F.R.§1.740(a)(15)**

All correspondence relating to this application for patent term extension should be addressed to:

Jennifer C. Chapman
Novartis
One Health Plaza, Bldg. 101
East Hanover, NJ 07936-1080

17. **Certification Under 37 C.F.R.§1.740(b)**

The undersigned hereby certifies that the instant application, including its attachments and supporting papers, is being submitted as one original and two copies thereof in accordance with 37 C.F.R.§1.740(b).

Respectfully submitted,

Jennifer C. Chapman

Novartis
Patents Pharma
One Health Plaza, Building 101
East Hanover, NJ 07936-1080

Jennifer C. Chapman
Attorney for Applicant
Reg. No. 47,487
(862) 778-1202

Date: November 16 2009

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Novartis AG

Application No./Patent No.: ~~08/216,440 / 5,677,331~~ Filed/Issue Date: March 23, 1994/Oct14, 1997

Titled: ANTIMALARIAL COMPOSITIONS

Institute of Microbiology and Epidemiology, Academy of Military Medical Sciences/ Novartis/AG, a University/Corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☐ the assignee of the entire right, title, and interest in;

2. ☐ an assignee of less than the entire right, title, and interest in (The extent (by percentage) of its ownership interest is _____ %), or

3. ☐ the assignee of an undivided interest in the entirety of a complete assignment from one of the joint inventors was made in the patent application/patent identified above, by virtue of either:

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

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The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Signature: Jennifer Chapman

Oct. 15, 2009
~~Oct. 15~~, 2009
Date

Cao, Wuchun/Jennifer Chapman
Printed or Typed Name

Director/Patent Attorney
Title

PTO/SB/81 (04-09)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	08/216,440
Filing Date	March 23, 1994
First Named Inventor	Yiqing Zhou
Title	ANTIMALARIAL COMPOSITIONS
Art Unit	1614
Examiner Name	Jordan, Kimberly R.
Attorney Docket Number	18634-US-CNT2

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

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01095

OR

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Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name

Address			
City		State	Zip
Country			
Telephone		Email	

I am the:

☐ Applicant/Inventor.

OR

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on:

SIGNATURE of Applicant or Assignee of Record

Signature		Date	Oct. 15, 2009 11/21/2009
Name	Cao, Wuchun/Jennifer Chairman	Telephone	862 778-1202
Title and Company	Institute of Microbiology and Epidemiology, Academy of Military Medical Sciences/Novartis AG		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*

☒ *Total of 1 forms are submitted

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